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## **VIA CM/ECF AND HAND DELIVERY**

The Honorable Gregory B. Williams U.S. District Court for the District of Delaware J. Caleb Boggs Federal Building 844 N. King Street Wilmington, DE 19801-3555

Re: *Jazz Pharms., Inc., et al. v. Avadel CNS Pharms., LLC*, C.A. Nos. 21-691, 21-1138 & 21-1594-GBW

Dear Judge Williams:

Pursuant to the Court's September 21, 2022 Oral Order (D.I. 180), counsel for the parties write jointly to further update Your Honor regarding proceedings before the Honorable Amit P. Mehta of the United States District Court for the District of Columbia in *Avadel CNS Pharmaceuticals, LLC v. Becerra, et al.*, C.A. No. 22-2159 (D.D.C.).

As described in the parties' October 18<sup>th</sup> letter, the Court heard arguments from Avadel, Jazz, and the FDA on October 7, 2022, regarding Avadel's request that the D.C. Court set aside the FDA's decision ordering Avadel to submit a patent certification for Jazz's U.S. Patent No. 8,731,963. During that hearing, the Court inquired as to each parties' position regarding the threshold question of whether Avadel has an adequate alternative remedy at law via its counterclaim in this case.

Yesterday, November 3, 2022, the Court issued a decision in this case that denied Avadel's request for relief, holding that "Avadel is not entitled to relief under the APA because of the availability of adequate alterative relief—namely, the ongoing, statutorily prescribed patent infringement and counterclaim proceedings in the District of Delaware." *Avadel*, C.A. No. 22-2159, D.I. 41 at 3. Because the Court determined that "Avadel has another adequate remedy at law and therefore cannot state an APA claim," the Court did not reach the FDA or Jazz's other arguments. *Id.* at 7. A copy of the Court's decision is attached hereto.

Respectfully submitted,

/s/ Daniel M. Silver

Daniel M. Silver (#4758)

cc: All counsel of record (via CM/ECF and E-Mail)

Enclosure